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In re Application of	:	
ABE et al	:	
Serial No.: 09/836,705	:	Decision on Petition
Filing Date: 17 April 2001	:	
Attorney Docket No. 01149/HG	:	

This letter is in response to the Petition filed on 8 October 2003, under 37 CFR 1.144 to review the restriction requirement. The delay in acting upon this petition is regretted.

BACKGROUND

This application was filed with 55 claims. On 19 February 2003, the examiner restricted the claims into 21 groups as follows.

> Restriction to one of the following inventions is required under 35 U.S.C. 1 121:
> I. Claims 1-4, 8-10, 13-17, 23-34, and 54, drawn to polynucleotides, vectors, and host cells relating to SEQ ID No: 37/38, classified in class 435, subclass 252.3.
>
> II. Claims 1, 5-7, 8, 11, 12, 18-34, and 55, drawn to polynucleotides, vectors, and host cells relating to SEQ ID No: 41/42, classified in class 435, subclass 252.3.
>
> III. Claims 35-37, drawn to polypeptides relating to SEQ ID N0: 38, classified in class 435, subclass 195.
>
> IV. Claims 35, 38, and 39, drawn to polypeptides relating to SEQ ID NO: 42, classified in class 530, subclass 350.
>
> V. Claims 40-43, 45, drawn to methods of producing ML-236B or pravastatin using SEQ ID NO: 37, classified in class 435, subclass 156.

VI. Claims 40-43, 45, drawn to methods of producing ML-236B or pravastatin using SEQ ID NO: 41, classified in class 435, subclass 156.

VII. Claim 44, drawn to ML-236B compound, classified in class 435, subclass 156.

VIII. Claim 46, drawn to antibodies to SEQ ID N0: 38, classified in class 530, subclass 387.1.

IX. Claim 46, drawn to antibodies to SEQ ID NO: 42, classified in class 530, subclass 387.1.

X. Claims 47-51, drawn to polynucleotides, vectors, and host cells relating to SEQ ID No: 43/44, classified in class 435, subclass 252.3.

XI. Claims 47-51, drawn to polynucleotides, vectors, and host cells relating to SEQ ID No: 45/46, classified in class 435, subclass 252.3.

XII. Claims 47-51, drawn to polynucleotides, vectors, and host cells relating to SEQ ID No: 47/48, classified in class 435, subclass 252.3.

XIII. Claims 47-51, drawn to polynucleotides, vectors, and host cells relating to SEQ ID No: 49/50, classified in class 435, subclass 252.3.

XIV. Claim 52, drawn to polypeptides relating to SEQ ID NO: 44, classified in class 435, subclass 183.

XV. Claim 52, drawn to polypeptides relating to SEQ ID NO: 46, classified in class 435, subclass 183.

XVI. Claim 52, drawn to polypeptides relating to SEQ ID NO: 48, classified in class 435, subclass 190.

XVII. Claim 52, drawn to polypeptides relating to SEQ ID NO: 50, classified in class 435, subclass 190.

XVIII. Claim 53, drawn to methods of producing ML-236B using SEQ ID No: 43/44, classified in class 435, subclass 156.

XIX. Claim 53, (drawn to methods of producing ML-236B using SEQ ID No: 45/46, classified in class 435, subclass 156.

XX. Claim 53, drawn to methods of producing ML-236B using SEQ ID N0s: 47/48, classified in class 435, subclass 156.

XXI. Claim 53, drawn to methods of producing ML-236B using SEQ ID No: 49/50, classified in class 435, subclass 156.

On 12 March 2003, Applicants elected Group VI (claims 40-43, and 45, drawn to method of producing ML-236B or pravastatin using SEQ ID No 41) with traverse. The examiner considered the traversal and made the restriction requirement **FINAL**. Claims 1-39, 44, 46-55 were withdrawn from consideration as non-elected inventions.

Claims 40-43 and 45 were rejected under 35 USC 112 first and second paragraph for indefiniteness. Claims 40, 42-43 and 45 were rejected under 35 USC 102(a) as being anticipated by WO 2001/12814.

On 8 October 2003, Applicants filed this petition along with an amendment to the claims.

DISCUSSION

The file record and petition have been reviewed carefully.

The petition proposes three different modifications of the Restriction Requirement each of which is discussed in turn:

First Proposed Grouping:

Rejoinder of Groups I to III, V to VII and X to XXI because all were classified in Class 435.

Rejoinder of Groups IV, VII (sic, VIII) and IX because both were classified in Class 530.

The first proposed grouping has been considered but is found to be not persuasive because classification of inventions by Class alone is not reflective of the burden entailed in searching the various inventions. It is noted that Groups I to III, V to VII and X to XXI were placed in one of Class 435, subclasses 252.3, 195, 156, 183 and 190, respectively. Furthermore, Groups IV, VIII and IX were placed in one of Class 530, subclasses 350 or 387.1, respectively. An extensive search of multiple inventions in more than one class/subclass would require undue search burden. Additionally, in the biotechnology art, classification is only indication of the burden of search. Literature searches in scientific journals along with sequence and structure searches of patent and non-patent databases is far more relevant for applications claiming molecules described in terms of nucleic or amino acid sequences. This arguments concerning the first proposed grouping is not perssauive.

Second Proposed Grouping.

Rejoinder of DNA Groups I, II and X to XIII because these are classified in Class 435, Subclass 252.3;

Rejoinder of "Method" Groups V to VII and XVII (sic, XVIIII) to XXI because these are classified in Class 435, Subclass 156;

Rejoinder of Antibody Groups VIII and IX because these are classified in Class 530, Subclass 387.1

Rejoinder of Polypeptide Groups III, IV and XIV to XVII because these are classified in Class 435, Subclass 183 or 190.

The second proposed grouping has been considered carefully but is deemed not to be persuasive for the following reasons.

While the DNA Groups are all placed in the same class and subclass, it is noted that Groups I, II, X, XI, XII and XIII are directed to nucleic acid related to SEQ ID Nos 37/38, 41/42, 43/44, 45/46 and 47/48, respectively. While there is some commonality with respect to the various nucleic acids in that they have been isolated from the same source species and that their encoded proteins are involved in ML-236B biosynthesis, this is not sufficient reason to rejoin the Groups. MPEP 803 states that

> Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 et seq.

Applicants may petition pursuant to 37 CFR 1.181 for examination of additional nucleotide sequences by providing evidence that the different nucleotide sequences do not cover independent and distinct inventions. However, if such a petition were filed and granted, prior art applied to one sequence may be applied under 35 USC 103, in view of applicant's admission.

"Method" Groups V, VI, XVIII, XIX, XX and XXI are directed to methods of using nucleic acid SEQ ID No 37, 41, 43, 45, 47 and 49, respectively. Each of these methods would require a search of the the particular sequence. Concurrent search and examination of the methods is burdensome for the reasons set forth above with regard to concurrent examination of the DNA productgroups. Group VII has been included in the proposed "Method" groups, however Group VII is not a method. Group VII contains product claims drawn to ML-236B compound, which is produced by the methods of claims V, VI, XVII-XXI. Similarly Group XVII is not a method, but is a product invention drawn to polypeptides which are neither made by or used directly in the methods of Groups V, VI, XVIII, XIX, XX and XXI. Concurrent examination of the "Method" groups would require undue search and examination burden.

Turning now to the Antibody Group, Group VIII is directed to antibodies that bind SEQ ID NO 38; Group IX is directed to antibodies which bind SEQ ID NO 42. The search for antibodies is not co-extensive and requires a text search of the scientific literature in addition to the sequence search for the structure of the antibody and the antigen and relevant search of the US and foreign patent databases. It is unlikely that applicants would accept prior art teaching an antibody which binds to SEQ ID No 38 on claims limited to an antibody that binds to SEQ ID NO 42. For these reasons, a concurrent examination of Group VIII and IX would require undue search burden.

Turning now to the "polypeptide Groups", it is noted that Groups III, IV XIV, XV, XVI and XVII are classified in Class 435, subclass 195, 350, 183, 183, 190, 190, and 156, respectively. These Groups are not classified in the same class and subclass and for this reason alone, rejoinder of these Groups would result in an undue search burden.

Third Proposed Grouping:

> Rejoinder of Groups V and VI because both share claims 40-43 and 45.
>
> Rejoinder of Groups VIII and IX because both share claims 46.
>
> Rejoinder of Groups XIV to XVII because all share claim 52.
>
> Rejoinder of Groups XVIII to XXI because all share claim 53.

Applicants request rejoinder of Groups that contain the same claims, citing MPEP 803.02. Applicants argue that the inventions should have been treated as an election of species, not as a restriction requirement.

MPEP 803.02 states in part

> If the members of the Markush group are sufficiently few in number or so closely related that a search and examination of the entire claim can be made without serious burden, the examiner must examine all the members of the Markush group in the claim on the merits, even though they are directed to independent and distinct inventions. In such a case, the examiner will not follow the procedure described below and will not require restriction. Since the decisions in In re Weber, 580 F.2d 455, 198 USPQ 328 (CCPA 1978) and In re Haas, 580 F.2d 461, 198 USPQ 334 (CCPA 1978), it is improper for the Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention. In re Harnish, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and Ex parte Hozumi, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Broadly, unity of invention exists where compounds included within a Markush group (1) share a common utility, and (2) share a substantial structural feature disclosed as being essential to that utility.

The original form of representative claims placed in two or more groups are set forth below.

Claim 40.

A method for producing ML-236B comprising
(a) culturing a host cell transformed by a vector comprising a polynucleotide encoding a protein having the amino acid sequence of SEQ ID NO 42, or a polynucleotide variant thereof encoding a modified amino acid sequence having at least one deletion, substitution or alteration, said polynucleotide variant being capable of increasing the transcription of a gene selected from the group consisting of mlcA, mlcB , mlcC and mlcD, said polynucleotide variant having at least an 80 % identity with SEQ ID NO 42, and
(b) recovering ML-236B from the resultant culture.

Claim 46

An antibody reactive with the protein of SEQ ID NO 38 or SEQ ID NO 42.

Claim 52.

A polypeptide encoded by a polynucleotide according to claim 47 or 48.

Claim 53.

A method for the production of ML236B comprising culturing a host cell according to claim 51 and then recovering ML-236B from the culture.

It is noted that Claims 52 and 53 depend, directly or indirectly, upon claim 47, as follow.

Claim 47.

A polynucleotide encoding a protein having the amino acid sequence selected from the group consisting of SEQ ID NO SEQ ID NO 46, SEQ ID NO 48 and SEQ ID NO 50, or a variant polynucleotide encoding a modification said amino acid or sequence having a deletion, substitution, addition alteration, said variant polynucleotide being capable accelerating the biosynthesis of ML-236B.

The third proposed grouping has been considered carefully but is deemed not to be persuasive for the following reasons. MPEP 803.02 requires that compounds included within a Markush group (1) share a common utility, and (2) share a substantial structural feature disclosed as being essential to that utility. The products listed in or used in each of the proposed groups do not share a common utility and/or a substantial structural feature disclosed as being essential to that utility

Fr example, claim 46 recites two products, in the alternative, which have been placed in Groups VIII and IX. The antibodies of claim 46 do not share a common utility because an antibody that binds to the protein having SEQ ID NO 38 is not required to a protein having SEQ ID No 42. Moreover, the antibodies which bind to protein having SEQ ID NO 42 is not required to a protein having SEQ ID No 38.

Furthermore, the products encompassed by Claim 46 do not meet the requirement of a Markush group because there is no particular required substantial structural feature shared among the products. The antibodies of Claim 46 share not common disclosed structure.

Turning now to Groups XIV-XVII and XVIII-XXI, which ultimately refer back to claim 47, the products of Claim 47 do not meet the requirement of a Markush group because there is no particular required substantial structural feature shared among the products. The polynucleotides of Claim 47 may have a common utility, the property of accelerating the biosynthesis of ML-236B, however, no structure is disclosed or claimed as being essential to that utility. MPEP 803.02 does not require an election of species among various methods of using products which fail to have "unity of invention."

Thus, rejoinder of Groups V and VI directed to claims 40-43 and 45, rejoinder of Groups VIII and IX, directed to claim 46, rejoinder of Groups XIV to XVII directed to claim 52 and rejoinder of Groups XVIII to XXI directed to claim 53 is not required by MPEP 803.02, Markush practice and would result in undue search burden.

Applicants argue that there is a commonality with respect to the two genes in that they are both polynucleotides from the same source species and that their encoded proteins are involved in ML-236B biosynthesis. However, the source from which a product is isolated is immaterial to patentable distinction and to the search burden, because identical products may be isolated from different sources. Similarly, the purported common property, involvement in ML-236B biosynthesis, is an insufficient reason to require concurrent examination because many unrelated and patentably distinct proteins may be involved the various steps of any biosynsthetic pathway. Thus the examiner was correct in requiring a restriction requirement, not an election of species, among the various inventions.

The amendment filed 8 October 2003 presents new claims 56-60, which will be examined along with the elected invention, because the SANK 7599 contains elected sequence SEQ ID No. 41.

DECISION

The petition is **DENIED** for the reasons set forth above.

Any request for reconsideration of this decision must be made by a renewed petition and must be filed within **TWO MONTHS** of the mailing date of this decision in order to be considered timely.

Applicants remain under obligation to reply to the time period set forth in the Final rejection mailed January 16, 2004.

Should there be any questions with regard to this letter, please contact Special Program Examiner Julie Burke by letter addressed to the Director, Technology Center 1600, P.O. Box 1450, Alexandria VA, 22313-1450 or by telephone at (571) 272-1600.

Bruce Kisliuk
TC1600 Group Director